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2 510(k) Summary

APR 30 2010

Date Prepared: March 31, 2010

Submitter's Name / Contact Person

Manufactured for
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Jennifer Ruether
Sr. Regulatory Affairs Associate
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General Information

Trade Name	VSI Torque Device
Common / Usual Name	Torque Device
Classification Name	870.1330 Wire, Guide, Catheter; Class II
Predicate Devices	K032411 Wire Vise (JS Vascular, Inc.) K021243 ILT Torquer (IntraLuminal Therapeutics, Inc.) K092711 Guidewire Torquer (Zerusa Limited)

Device Description

The VSI Torque Device is a two-part oblong-shaped, medical grade plastic device designed to be used with guidewires ranging in size from 0.014" – 0.038". The two halves of the torque device snap together and the device is then placed onto a guidewire. One half of the device is rotated to lock it onto the guidewire. The VSI Torque Device provides additional control of the movement of the guidewire.

Intended Use / Indications

The VSI Torque Device is intended for use in manipulating a guidewire that is in the vasculature.

Technological Characteristics

The VSI Torque Device, the Zerusa Guidwire Torquer, and the Wire Vise use a pin vise clamp as the mechanism to lock the torque device onto a guidewire. The VSI Torque Device and the predicate devices have similar guidewire compatibility, and the Wire Vise has the same range of guidewire compatibility as the VSI Torque Device. The VSI Torque Device and the Zerusa Guidewire Torquer consist of the same design and material of construction (medical grade plastic material, Celanex 2401 MT). The VSI Torque Device and the ILT Torquer are sterilized in an ethylene oxide process, and have similar sterile barrier packaging materials.

Substantial Equivalence and Summary of Studies

The VSI Torque Device is substantially equivalent in intended use and indications to the predicate devices. The device design has been qualified through tensile and torque testing, dimensional verification, and visual inspection to verify the performance of the device. A biomaterial assessment was conducted in accordance with ISO 10993; because the torque device does not come into direct or indirect contact with the patient, no biocompatibility testing was required. The results of the verification testing and biomaterial assessment did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 30 2010

Vascular Solutions, Inc.
C/O Ms. Jennifer Ruether
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K100093
Trade/Device Name: VSI Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 13, 2010
Received: April 14, 2010

Dear Ms. Ruether:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100093

Device Name: VSI Torque Device

Indications for Use:

The VSI Torque Device is intended for use in manipulating a guidewire that is in the vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100093